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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/595,033

01/04/2006

Warren Ward

WAW0101PUSA

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EXAMINER

KASSA, TIGABU

ART UNIT

PAPER NUMBER

1619

MAIL DATE

DELIVERY MODE

01/07/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/595,033	Applicant(s) WARD, WARREN	
	Examiner TIGABU KASSA	Art Unit 1619	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 September 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) 1-6, 12-23 and 34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7-11 and 24-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>06/13/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 7-11, 24-33, and 35 are pending. Claims 1-6, 12-23, and 34 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claims.

Election/Restrictions

Applicant's election with traverse of Group V (claims 7-11, 24-33, and 35) in the reply filed on 09/19/08 is acknowledged. The traversal is on the ground(s) that the prior art reference used for breaking unity Herbig et al. (U.S. Patent No. 5,798,119, column 6, lines 51-67) does not anticipate claim 7, because it does not teach a coating with “liquid impermeable but gas permeable” property. This is not found persuasive because of the reasons mentioned in the previous office action mailed on 08/21/08.

The requirement is still deemed proper and is therefore made FINAL.

Priority

The earliest effective filing date afforded for the instantly claimed invention, has been determined to be 12/22/04, the filing date of the instant application.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 06/13/06 was noted and the submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the examiner has considered the information disclosure statement.

Claim Rejections - 35 USC §101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The claimed invention lacks patentable utility. The instant application fails to provide adequate evidence to support the utility of the invention. Specifically, there is insufficient evidence to show that a compound which is not released on or into the body can have any medically beneficial effect. Additionally, the agents used to form the liquid impermeable but gas permeable layer (e.g. wax) are also used in the art to form controlled release formulations of drugs. There is insufficient evidence to support the assertion that the medically efficacious substance does, in fact, show (i) no metabolic change (ii) no chemical change, and (iii) no diminution in its quantity in the formulation.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with

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which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7-11, 24-33, and 35 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the coating to be liquid impermeable, does not reasonably provide enablement for the encapsulating layer as gas permeable. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to ascertain the gas permeability of the coating layer the invention commensurate in scope with these claims. While the applicant states, in the specification, that the encapsulating layer is liquid impermeable but gas permeable, the applicant provides no evidence whatsoever that the encapsulating layer is, in fact, gas permeable. The only evidence for liquid impermeability provided in the specification is also for aqueous media and not for other liquids.

Claims 7-11, 24-33, and 35 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains,

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or with which it is most nearly connected, to use the invention. The specification does not reasonably provide enablement for how to use the claimed preparation or composition for the treatment of diseases. Applicant does not provide adequate evidence to substantiate the fact that a drug coated such that the drug undergoes no metabolic change, no chemical change, and no diminution in its quantity is effective. Applicant provides no evidence to substantiate the assertion that a drug which is not released is effective at treating any diseases.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: 1) scope of breadth of the claims; 2) nature of the invention; 3) relative level of skill possessed by one of ordinary skill in the art; 4) state of, or the amount of knowledge in, the prior art; 5) level or degree of predictability, or a lack thereof, in the art; 6) amount of guidance or direction provided by the inventor; 7) presence or absence of working examples; and 8) quantity of experimentation required to make and use the claimed invention based upon the content of the supporting disclosure. When the above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

Scope or breadth of the claims

The breadth of the claim is a medically efficacious substance which is coated with a liquid impermeable but gas permeable layer such that the medically efficacious substance shows no metabolic change, no chemical change, and no diminution in its quantity.

Nature of the invention

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The nature of the invention is directed to the treatment of blocked or malfunctioning exocrine glands using a medically efficacious substance coated in a liquid impermeable but gas permeable layer.

Relative level of skill possessed by one of ordinary skill in the art

The relative level of skill possessed by one of ordinary skill in the art of medical research is relatively high, as a majority of lead investigators conducting scientific research and development in this particular area possess M.D. and/or Ph.D. in a scientific discipline such as medicinal chemistry, biochemistry, pharmacology, biology, organic synthetic chemistry or the like.

State of, or the amount of knowledge in, the prior art

The art teaches the coating of drugs or other medically efficacious substances for controlling the release of the drug. Coated drugs are well known and include, e.g., aspirin (US patent 4508702, abstract); applicant teaches the use of coated aspirin in example 3 in the specification. The prior art does not recognize the treatment of diseases with drugs which are never released.

Level or degree of predictability, or a lack thereof, in the art

Currently, there are well established methods of coating drugs. Specifically, the use of polymers, ceramics and waxes including natural wax and beeswax for coating drugs are known in the art (US Patent No 5827538, see the whole document). However, even drugs coated with polymers, ceramics and waxes including natural wax and beeswax are designed for the controlled release of the encapsulated drug. No prior art, however, teaches a coated drug which is

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not released upon administration. Moreover, the no prior art predicts that such a drug which is not released would be efficacious.

Presence or absence of working examples

The specification fails to provide scientific data and working examples with respect to the effectiveness of the coated drugs which are not released. The information provided in the examples does not meet the currently accepted scientific standards for determining the efficacy of new pharmaceutical compositions. The currently accepted practice uses double blind controls in which one group receives the new drug and a control group receives a placebo; neither group knows whether it receives a placebo or the new drug being tested. The examples given in the specification do not have control groups. Moreover, patients know when they are receiving the ActivSignal form versus the standard form of the drug. Additionally, the agitation of coated medically efficacious substances in acidic or alkaline water is inadequate to justify the assertion that the coating is impermeable to liquids generally. It is also inadequate to ensure that the medically efficacious substance is not released upon administration to the subject since acidic and basic water do not adequately simulate all biological fluids that might be encountered by the coated medically efficacious substance upon administration to a subject. Moreover, applicant fails to specify the acid or base used and the pH of the resulting solution.

Quantity of experimentation required to make and use the claimed invention based upon the content of the supporting disclosure

As a result, one of ordinary skill in the art would be required to conduct an undue amount of experimentation to reasonably and accurately determine whether the composition of the

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instant application is not released and moreover to determine whether a drug which is not released is effective.

Claims 7-11, 24-33, and 35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The Examiner was unable to ascertain the meets and bounds of the claimed invention because as written the claims are vague and indefinite. The claims as written, therefore, are unsearchable. Therefore, the examiner did not apply any art in the rejection of the claimed invention at this time.

Conclusion

Claims 7-11, 24-33, and 35 are pending, while claims 1-6, 12-23, and 34 are withdrawn.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TIGABU KASSA whose telephone number is (571)270-5867. The examiner can normally be reached on 9 am-5 pm Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patrick Nolan can be reached on 571-272-0847. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Tigabu Kassa

12/31/08

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/Johann R. Richter/

Supervisory Patent Examiner, Art Unit 1616